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GROUP 1600 **PATENT**
Docket No. P-3250IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**OFFICIAL**

APPLICANT(S): R. Campbell, P. Haaland, D. Sherman, W. Stewart and Sheila Lloyd
SERIAL NO. 09/359,260 ART UNIT: 1627
FILING DATE: July 22, 1999 EXAMINER: Ricigliano, J.
TITLE: Methods, Apparatus and Computer Program Products for Formulating Culture Media

Assistant Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on the date shown below.

On: October 12, 2000
By: Donna Baumann

Donna M. Baumann 10-12-00
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RESPONSE TO REQUIREMENT FOR RESTRICTION AND SPECIES ELECTION

This is in response to the Official Action mailed September 12, 2000, requiring restriction and election of species in the subject patent application. The response is due by October 12, 2000. The Examiner has identified nine inventions among the claims of the application: Group I (Claims 1-15, 18-30), Group II (Claims 31-35), Group III (Claims 36-40), Group IV (Claims 41-54, 57-58), Group V (Claims 16-17, 55-56, 113-118), Group VI (Claims 59-73), Group VII (Claims 74-95), Group VIII (Claims 96-112, 127) and Group IX (Claims 119-122, 123-126).

ELECTION OF INVENTION

Applicants elect the invention of Group VII, with traverse as discussed below.

REASONS FOR TRAVERSE OF RESTRICTION REQUIREMENT

The Examiner asserts that the inventions of Groups I, IV and VIII are distinct because they require different steps. Applicants respectfully submit that the mere inclusion of different steps is not sufficient to make the inventions defined by various claims distinct. In this case, the independent claim of each group recites the same basic steps and these steps define the core of the invention: measuring first indicia of a property, determining a relationship between at least one parameter and the measured

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first indicia, determining a test requirement relating to the measured first indicia, and (based on the relationship) identifying additional compounds expected to provide indicia which meet the test requirement. These steps define the same essential characteristics of a single disclosed embodiment of the invention. Additional steps such as culturing do not result in distinct inventions, but only vary the scope of the same invention as claimed. Therefore Groups I, IV and VIII are merely different definitions of the same disclosed subject matter. Under such circumstances restriction should never be required (MPEP §806.03). Accordingly, the requirement for restriction between the invention of Group I, the invention of Group IV and the invention of Group VIII should be withdrawn.

With respect to the requirement for restriction between Groups I, IV and VIII and Group V, the Examiner relates these groups as product and process of use. However, the products of Group V are produced by, not used in the methods of Groups I, IV and VIII. The independent claims of Group V clearly recite that the claimed product is produced by the claimed method. The analysis supporting the reasons for restriction is therefore in error. A correct analysis of process of making and product made involves determining whether the claimed process can be used to make a materially different product or the claimed product can be made by a materially different process. In this case, the compounds of Group V cannot be made by a materially different process because they are product-by-process claims which recite the processes claimed in Groups I, IV and VIII. Further, the process of Groups I, IV and VIII results in identifying the culture medium component of Group V, so the process cannot be used for making a materially different product. The invention of Groups I, IV and VIII and the invention of Group V are therefore not distinct and the restriction requirement with respect thereto should be withdrawn.

With respect to the requirement for restriction between Groups I, IV and VIII and Groups VI and VII, Applicants again submit that the independent claim of Group VII and the independent claim of each of Groups I, IV and VIII recites the same basic steps and that these steps define the core of the invention: measuring first indicia of a property, determining a relationship between at least one parameter and the measured first indicia, determining a test requirement relating to the measured first indicia, and (based on the relationship) identifying additional compounds expected to provide indicia which meet the test requirement. These steps define the same essential characteristics of a single disclosed embodiment of the invention. Differences in claim language between the groups such as "parameter" vs. "whole molecule parameter", "compound" vs. "peptide" and whether or not the method is performed in culture media do not create distinct inventions, but simply vary the scope of the same invention as claimed. Therefore Groups I, IV and VIII and Group VII are merely different definitions of the same disclosed subject matter. Under such circumstances restriction should never be required (MPEP §806.03). Accordingly, the requirement for restriction between the invention of Groups I, IV and VIII and the invention of Group VII should be withdrawn.

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Group VI represents a subcombination of the combination claims of Groups I, IV and VIII in that it recites the two basic steps of the invention which result in predicting the activity of a peptide (i.e., measuring indicia and determining a relationship). This predicted activity information is then used in the combination method of Groups I, IV and VIII to identify peptides which are expected to meet a selected test requirement. The specific characteristics of the subcombination are also set forth in the combination claims. There is therefore no evidence that the combination is patentable without the details of the subcombination, and restriction between the invention of Group VI and the invention of Groups I, IV and VIII should not be required (MPEP §806.05(c)).

With respect to the requirement for restriction between Groups II and III, related as process of making and product made, the Examiner is in error in concluding that the library can be made by methods other than the recited process. The claimed process requires only the step of "representing each of a plurality of groups of compound isomers from within a compound space as a respective candidate compound." The claimed product is a library wherein the only limitation is that "each of a plurality of compound isomers from within a compound space is represented as a respective candidate compound." Applicants respectfully submit that it is not possible to create a library of candidate compounds representing each of a plurality of groups of compound isomers by any other method than representing each of the plurality of groups of compound isomers as such candidate compounds. Distinctness between process and product has therefore not been shown and the requirement for restriction between the invention of Group II and the invention of Group III should be withdrawn.

With respect to the requirement for restriction between Group VI and Group VII, Group VI also represents a subcombination of the combination claims of Group VII in that it recites the two basic steps of the invention which result in predicting the activity of a peptide (i.e., measuring indicia and determining a relationship). This predicted activity information is then used in the combination method of Group VII to identify peptides which are expected to meet a selected test requirement. The specific characteristics of the subcombination are also set forth in the combination claims. There is therefore no evidence that the combination is patentable without the details of the subcombination, and restriction between the invention of Group VI and the invention of Group VII should not be required (MPEP 806.05(c)).

CONCLUSION ON RESTRICTION

If the various restriction requirements are withdrawn as Applicants request, the claims of the present application would represent three inventions, as follows:

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First Invention: Groups I, IV, V, VI, VII and VIII
Second Invention: Groups II and III
Third Invention: Group IX

Applicants request reconsideration of the restriction requirement and regrouping of the claims as suggested above.

ELECTION OF SPECIES

In connection with Applicants' election of the invention of Group VII, election of species relating to functions for performing the method, parameters and peptide activities is required. With respect to the election of a "function" species, Applicants elect the function $y_1 = f(x_4)$ as set forth in Claim 76. Claims 74-79 and 81-95 are readable on the elected "function" species and Claim 74 is generic to it. With respect to the election of an "at least one whole molecule parameter" species, Applicants elect three whole molecule parameters for use in the method, i.e., molecular weight, hydrophobicity and total charge. Claims 74-95 are readable on the elected "parameter" species and Claim 74 is generic to it. With respect to the election of an "activity" species, Applicants elect enhancement of β -toxin production. Claims 74-86, 88, 90-91 and 94-95 are readable on the elected "activity" species, and Claim 74 is generic to it.

Respectfully submitted,

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